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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
YASUSHI SHIOYA, ET AL. : EXAMINER: CORBIN, A.L.  
SERIAL NO: 10/518,372 :  
FILED: DECEMBER 28, 2004 : GROUP ART UNIT: 1794  
FOR: BEVERAGE:

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Tatsuya Kusaura who deposes and states that:

1. I am a graduate of Shinshu university, and received my master degree in the field of chemistry, in the year 2000.
2. I have been employed by Kac Corporation, for 7 years in the field of research of health care.
3. I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.
4. I am a named inventor of the above-identified application.
5. The following experiments were carried out by me or under my direct supervision and control.
6. The following experiments demonstrate the criticality of maintaining the ratio of hydroxycarboxylic acid content to chlorogenic acid content within the range of 5 to 15. In this demonstration, samples in which the ratio of hydroxycarboxylic acid content to chlorogenic acid content is within the range of 5 to 15 was directly compared to Example 9 of Okawa et al (US 2002/0022062) where the corresponding ratio is 19.8.

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7. The coffee bean extract used in Example 9 of Okawa et al ("Flavor Holder FH1041" from T. Hasegawa Co. Ltd.) contains 28.1 wt% of chlorogenic acid. The chlorogenic acid content in FH1041 and the other disclosed coffee bean extracts is calculated as follows:

In paragraph [0021], Okawa et al disclose the preparation of the extracts from coffee beans used in their Examples. Specifically, paragraph [0021] discloses::

From "Flavor Holder FH1041" (trade name of a food additive; product of T. Hasegawa Co., Ltd.; Coffee Bean Extract 3), an eluate was obtained using a cationic exchange column (for example, "SK-1B", trade name; product of Mitsubishi Chemical Co., Ltd.), followed by concentration into Coffee Bean Extract 4. Caffeine was extracted from the column and the extract was added to the coffee bean extract for ingredient adjustment, whereby Coffee Bean Extracts 1 and 2 were prepared.

In paragraph [0022], Okawa et al disclose the "dry solid contents of Coffee Bean Extracts prepared by the above-described process and amounts of chlorogenic acid and caffeine contained in them are shown in Table 1". Table 1 (below) reflects Table 1 of Okawa et al and has been expanded to include the amount of chlorogenic acid and caffeine in the extract:

Table 1

	Dry solid content %	Chlorogenic and caffeine in Extract	Chlorogenic / caffeine ratio	Chlorogenic acid % in Extract	Caffeine % in Extract
	Content %	Total %	Ratio	%	%
Extract 1	71%	51%	1.2	27.8%	23.2%
Extract 2	58%	39%	2.5	27.9%	11.1%
Extract 3	53%	34%	4.8	28.1%	5.9%
Extract 4	48%	29%	28.0	28.0%	1.0%

In Table 1 above, the content of the chlorogenic acid in the extract (using Extract 3 as an example) is calculated as follows:

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$$(4.8)/(4.8+1.0)*34\% = \text{chlorogenic acid \% in extract}$$

Thus, looking at Example 9 (paragraph [0045]) of Okawa et al, it is possible to calculate the ratio of hydroxycarboxylic acid content to chlorogenic acid content as follows:

Vitamin C ( ascorbic acid)	2000mg (4% in drink)
Flavor Holder (FH1041)	360mg
→Chlorogenic acid content 28.1%	101mg (0.202% in drink)
total amount 5	0mL
(b) Vitamin C / (a) Chlorogenic acid =	19.77

More precisely, the ratio of hydroxycarboxylic acid (Vitamin C) to chlorogenic acid in the compound of Example 9 is calculated as:

$$2000\text{mg} / (360\text{mg} \times 0.281) = 2000/101.16 = 19.77$$

This ratio does not fall within the claimed range (5 to 15).

8. To demonstrate the criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content is within the range of 5 to 15, the following procedure was followed:

(a) Experiments

Experiments 2 to 5: Products with (b)/(a) ratio within the range of 5 - 15  
Experiments 1 and 6 to 8: Reference Products with (b)/(a) ratio outside the range of 5 - 15

- Exp. 1: Comparative Example 6 of the present application
- Exp. 2: Example 7 of the present application
- Exp. 3: Example 3 of the present application
- Exp. 4: currently added (a composition of the present invention)
- Exp. 5: currently added (a composition corresponding to Okawa with (b)/(a) ratio of 15)
- Exp. 6: currently added (a composition corresponding to the invention expect that (b)/(a) ratio was 19.8)
- Exp. 7: Example 9 of Okawa ((b)/(a) = 19.8)
- Exp. 8: Comparative Example 3 of the present application

(b) Evaluation

(i) Dreg formation (25°C, 24 hours)

Evaluation method and criteria were the same as described at page 8, lines 14-21 of the specification for the above-identified application.

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#### Rating

- 1: No dreg formation was observed.
- 2: Dreg formation was observed a little.
- 3: Dreg formation was observed definitely

(ii) Storage stability (long term stability, suggested at page 14, lines 10-11 of the specification for the above-identified application)

Evaluation was performed after storage for 7 days at 60°C.

Evaluation criteria:	color darkened	: 3
	color slightly darkened	: 2
	color not changed	: 1

(iii) Taste, Astringency, Bitterness, and Foreign taste

Evaluation methods were the same as described at page 7, line 32 to page 8, line 2 of the specification for the above-identified application.

Evaluation criteria of "Taste" was the same as described at page 8, lines 6-13 of the specification for the above-identified application.

Evaluation criteria of "Astringency"	Astringency is felt very strongly	: 4
	Astringency is felt strongly	: 3
	Astringency is felt	: 2
	Astringency is slightly felt	: 1
	Astringency is not felt at all	: 0
Evaluation criteria of "Bitterness"	Bitterness is felt very strongly	: 4
	Bitterness is felt strongly	: 3
	Bitterness is felt	: 2
	Bitterness is slightly felt	: 1
	Bitterness is not felt at all	: 0
Evaluation criteria of "Foreign taste"	Foreign taste is felt very strongly	: 4
	Foreign taste is felt strongly	: 3
	Foreign taste is felt	: 2
	Foreign taste is slightly felt	: 1
	Foreign taste is not felt at all	: 0

9. Table 2 shows the results obtained from these experiments:

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Experiment No.	1	2	3	4	5	6	7	8
corresponding to:	Com.Ex. 6 in the present application	Example 7 in the present application	Example 3 in the present application	Example 9 in the present application	Example 3 in the present application	Example 9 in the present application	Example 3 in the present application	Example 9 in the present application
(Material comprising chlorogenic acid)	360 mg (%)	250 mg	235 mg (%)	475 mg (%)	235 mg (%)	360 mg (%)	375 mg (%)	375 mg (%)
isochlorogenic acids	16 mg	20 mg	10 mg	19 mg	10 mg	14 mg	8 mg	8 mg
(a) Total chlorogenic acids	106 mg	140 mg	70 mg	133 mg	70 mg	101 mg	52 mg	52 mg
isochlorogenic acids	1/7	1/7	1/7	1/7	1/7	1/7	1/7	1/7
content ratio								
Citric acid	300 mg	250 mg	350 mg	350 mg	350 mg	350 mg	2000 mg	2000 mg
Malic acid	-	100 mg	100 mg	350 mg	350 mg	350 mg	-	-
Sodium citrate	20 mg	450 mg	350 mg	350 mg	350 mg	350 mg	-	-
Vitamin C (ascorbic acid)	30 mg	-	-	2000 mg	2000 mg	2000 mg	-	-
(b) Total hydroxycarboxylic acid	350 mg	800 mg	1050 mg	2000 mg	2000 mg	2000 mg	2000 mg	2000 mg
(c) water	97.69 g	96.23 g	97.365 g	50 g in total	97.365 g	50 g in total	97.626 g	97.626 g
Apple juice (%)	-	-	-	-	-	-	4.4 g	4.4 g
Fructose-glucose (%)	1.5 g	1.5 g	1.5 g	1.6 g	1.6 g	1.6 g	1.6 g	1.6 g
Sucrose	-	-	-	11 g	-	11 g	-	-
Perfume	0.1 g	0.1 g	0.1 g	-	0.1 g	-	0.1 g	0.1 g
pH	3.0	4.6	3.8	3.0	3.2	3.0	1.5	1.5
Etch	1.47	1.65	1.30	24.3	1.68	24.0	3.69	3.69
<Evaluation>								
Taste	3	1	0	0	2	2	3	3
Astringency	1	0	0	0	2	2	3	3
Bitterness	2	0	0	0	1	0	1	1
Foreign taste	3	1	0	0	0	0	0	0
Drug formation	1	1	1	1	1	1	1	1
Storage stability (%)	2	1	1	1	1	1	2	2

\*2 Amonol Apple Juice, 5-fold condensed (malic acid content 2.50)

\*4 Joint Association of Agricultural Cooperatives of Etiline

\*5 Raw coffee beans extract

\*6 Evaluation after storage for 7 days at 80 °C

Rating of Taste, astringency, bitterness, and foreign taste:

4: felt very strongly

3: felt strongly

2: felt

1: slightly felt

0: not felt at all

Rating of Drug formation:

3: observed definitely

2: observed a little

1: no drug was observed

Rating of Storage stability:

3: color darkened

2: color slightly darkened

1: color not changed

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10. The data above clearly illustrates the criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content within the range of 5 to 15. Specifically, the data above demonstrate that when the weight content of the ingredient (b) was higher than 15 times the weight of the ingredient (a) (experiment numbers 6-8), the beverage resulted in an overly acid flavor, rendering the beverage unfit for long-lasting drinking. When the weight content of hydroxycarboxylic acids (of ingredient (b)) was lower than 5 times the weight of the ingredient (a) (experiment number 1), the beverage exhibited astringency, bitterness or foreign taste. The criticality of the ratio of hydroxycarboxylic acid content to chlorogenic acid content within the range of 5 to 15 is unexpected.

11. Certainly the foregoing beneficial effects are not predictable from the disclosures of Okawa et al (US 2002/0022062), which discloses a ratio of hydroxycarboxylic acid content to chlorogenic acid content of 19.8. Further, this result would not be predicated from the disclosure of Suzuki et al (EP 1 186 297), which only discloses the possibility of the presence of chlorogenic acid, generically discloses the content of chlorogenic acid, generically discloses the possibility of a hydroxycarboxylic acid, and generically discloses the content of the hydroxycarboxylic acid. Suzuki et al does not offer any guidance of a ratio of hydroxycarboxylic acid content to chlorogenic acid content ranging from 5 to 15. More importantly, Suzuki et al fails to provide any suggestion of the beneficial results flowing from this specific ratio as demonstrated above.

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12. I declare further that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

13. Further Declarant saith not

Tatsuya Kusaura  
Name:

December 12, 2008  
Date